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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
1743	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/831,260</b>	Applicant(s) <b>Wijnschenk et al.</b>	
	Examiner <b>Dwayne K. Handy</b>	Art Unit <b>1743</b>	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on \_\_\_\_\_.

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 13-24 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 13-18 and 20-24 is/are rejected.

7)  Claim(s) 19 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19)  Notice of Informal Patent Application (PTO-152)

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.  
(e) the invention was described in-  
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 13, 14, 20-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Picozza et al. (5,282,543). Picozza teaches a cover for sealing a plurality of reaction tubes comprised of a unitary body of flexible material having a plurality of nodules. Each nodule has a downwardly convex lower portion extending from a connected web for engaging the reaction tube at its opening. The device is best shown in Figures 4 and 5 and described in columns 5 and 6.
6. From columns 5 and 6:

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(8) A second embodiment of the cover in accordance with the present invention is shown in a top view in FIG. 3, and a partial side view in FIG. 4. Cover 50 is a planar array of individual reaction tube covers or nodules 52 arranged in a predetermined rectangular spatial arrangement corresponding to the centers of a corresponding planar array of reaction tubes held in a tray. Each of the individual covers or nodules 52 is made of a flexible plastic material and held in the predetermined spaced relationship from each other by an integral web 54. Web 54 may be integral with nodules 52 and made of the same material or may be made of a different material with the nodules 52 molded or adhesively attached to the web 54 at appropriate locations.....

..... (15) The cover portion 12 or nodules 50 are spaced on 9 millimeter centers corresponding to the standard array of 96 reaction tubes. The apertures are about 4 millimeters in diameter. It is to be understood that other spacings and sizes may be utilized depending on the reaction tube tray design. The preferred silicon rubber must be chemically resistant to dilute nitric acid, dilute sodium hydroxide, sodium hypochlorite (bleach), and ethanol having material hardness of Shore A 50, and must be autoclavable. Silicone rubber is preferable in this application as it is inert to the PCR products and reagents, is autoclavable, and is washable in a hypochlorite solution without substantial deleterious effects. A suitable silicone rubber material may be obtained by High Tech Rubber Company, Anaheim, CA.

(16) Other materials may also be utilized provided they are flexible, inert to reactions with the reagents utilized, and can withstand repeated thermal cycling to temperatures above 100 degree C. Also, the nodules may each have an internal filling of a high thermal conductivity material such as a metal "B-B" to increase the overall heat transfer through the nodules from the heated platen. The covers 10 and 50 in accordance with the present invention need not be utilized with a full tray of reaction tubes. For example, an array of 8 rows by 12 columns, totaling 96 tubes, may effectively be utilized with the cover in accordance with the present invention. However, the same sample tray containing any number of tubes will be adequately sealed with either of the covers in accordance with the present invention. Thus, the covers in accordance with the present invention can effectively replace the conventional cap strips and result in substantial time savings during handling.

3. Claims 13-15, 17, 18, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shami (4,599,314). Shami teaches a multiple vessel specimen tray with a lid for releasably adhering vessel covers. The device is best shown in Figures 2 and 3 and described in column 3.

From column 3:

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(6) FIG. 3 shows tray 20 in section with a series of vessels 22 in position in the openings in the tray. A lid for the tray is indicated at 44 and is shown partly removed from the tray. Since lid 44 is physically identical with tray 20, parts of the lid which correspond with parts of tray 20 already described in connection with FIG. 1 have been indicated by primed reference numerals in FIGS. 2 and 3. It will be seen from these views that the flanges 32' at the lower ends of the vertical end walls 30' of lid 44 rest on the extensions 28a of the top plate 28 of tray 20 with the projections 36 engaged in the openings 34' of the lid flanges 32'. In this way, the tray and lid are positively located with respect to one another and will not normally be separated other than by deliberately lifting lid 44 generally vertically.

(7) These projections and slots also allow several specimen tray apparatus to be stacked one on top of the other and positively located with respect to one another as best illustrated in FIG. 2. In that view, two apparatus each comprising a tray 20 and a lid 44 are shown stacked one on top of the other. Each apparatus is generally denoted by reference numeral 46 and the two trays and lids are denoted 20 and 44 respectively. It will be seen that the projections 36' of the lid of the lowermost apparatus 46 extend through the openings 34 of the tray of the dish above and thereby positively locate the two apparatus with respect to one another.

(8) A further feature of the apparatus is that the vessels 22 are designed so that, when lid 44 is in place on tray 20, the top walls 40 of the covers 24 will project into the openings 26' in the top plate 28' of the lid 44 and will lie with their top surfaces substantially even with the top surface of the remainder of plate 28', as best shown in FIG. 2. Pressure sensitive tape can then be applied over the top surface of plate 28' and the exposed surfaces of the covers 24 and will releasably secure the covers to the lid. FIG. 3 illustrates the covers being lifted with the lid. That view also shows how the pressure sensitive tape 48 can be peeled back as appropriate to release selected ones of the covers 24.

In Figure 3, then, Shami shows an upper tray or sheet (28) with openings covered by adhesive tape. The tape engages the top (40) of the covers (24) which are projected into the openings (26) of the plate. The Examiner also considers the addition of the tape to the upper place as meeting the limitation of claim 1 of a carrier sheet and sealing elements being made of different materials since the carrier contains an adhesive sheet while the covers do not. Shami also shows a groove in the cap formed by a skirt (42) which engages openings in the carrier sheet.

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4. Claims 13-16 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gamble (6,106,783). Gamble teaches a microplate assembly with a closure element comprised of an array of caps comprising a septum and sidewall having a vial engagement ring. The embodiments most relevant to applicant's device are best shown in Figures 1, 3, 4 and 9, and described in columns 3-5. Figure 1 shows a general embodiment of the device. Figure 3 shows an embodiment in which the closure and caps are comprised of different materials. The embodiment shown in Figure 3 is described in detail in column 3:

(8) FIG. 3 is a top view of closure 117 showing an 8.times.12 array of septum openings 135 in membrane 121. In the preferred embodiment, membrane 121 is made from a flexible polymeric material such as polyolefins. In other embodiments, membrane 121 is made of vinyl, natural or synthetic rubbers, or other elastomers. In the preferred embodiment, closure 117 is injection molded of polyethylene, resulting in caps (119 of FIG. 1) integral with membrane 121. Flap portions 303 project along edge 125D of closure 117, providing a surface which is easily engaged with the fingers of the hand to remove and replace closure 117 on vials 113. In other embodiments, flap portions or extended edge portions are provided on other edges of closure 117. Corners 123A and 123B may be chamfered as shown to aid in alignment of closure 117 to microplate 101 of FIG. 1. Chamfered corners also act as alignment means for storage and handling of groups of closures. In other embodiments, closure 117 is made of a rigid polymeric material.

(9) FIG. 4 is a side view and partial cross section of closure 117 taken at lines 4--4 of FIG. 3. Caps 119 comprise sidewall portion 403. Sidewall portion 403 is generally cylindrical and has an inner diameter 405 sufficient to fit over vials 113 of FIG. 1. In the preferred embodiment, the inner diameter of caps 119 comprise a flange engagement ring 407 protruding inside sidewall 403 for engaging flanges 115 of vials 113 to retain caps 119 on vials 113. Septum 408 comprising resealable portion 409 provides a seal between septum opening 135 and the vial (not shown).

Figure 9 shows an embodiment with detachable caps as well as strips or rows of connected caps for covering only part of the array. This embodiment is described in column 5:

(17) FIG. 9 is a perspective drawing of microplate 101 comprising 96 wells 103. Individual septum caps 901 are snapped on flanged vials 113 and inserted into wells 103. FIG. 9A is a detail cutaway drawing of cap 901 snapped over flange 115 of vial 113. Flange engagement ring 903 of cap 901 engages flange 115

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to retain cap 901 on vial 113. In the preferred embodiment, vial 113 is a loose fit in well 103. In other embodiments, vial 113 forms a snug fit in well 103.

(18) Cap strip 905 comprises 16 integral caps 907 on membrane 909, similar to those of FIGS. 1-6. Caps 907 may comprises septum openings 911. In other embodiments, cap strip 905 comprises one or more partial or full rows or columns of vial caps. Cap strip 905 allows separate use of only a portion of the vials and wells of microplate 101.

Gamble shows a sealing mat with a carrier sheet and sealing elements. The sealing elements are made of a chemically resistant material and may be detached from the mat.

5. Claims 13, 14, 20, 21, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Reo (6,558,628). Reo teaches a vial kit which is sealed by a vial pack cover which simultaneously covers a plurality of containers through the use of a plurality of plug portions depending from the bottom of the cover. The vial pack cover (36) is best shown in Figure 6. It's use is described in columns 4 and 5. Starting at column 6, line 65:

11) Once the materials have been inserted into the compartments, the user will then engage the vial pack cover 36 with the vial pack 28, and in the event vials 32 are used, with the vials 32 as well. Optionally, the vial pack 28 may include a ridge or groove 54. In such an embodiment, the ribbing 46, optionally disposed along the periphery of the support sheet 42 of the vial pack cover 36, will engage the ridge 54 to aid in retaining the vial pack cover 36 to the vial pack 28. It should be understood, however, that many equivalent variations exist for further securing the vial pack cover 36 to the vial pack 28. For example, a clamp(s) (not shown), complementary male and female connectors (not shown), snap connectors (not shown), or various adhesives (not shown) could be used.

(12) Once the vial pack cover 36 is secured over the vial pack 28, the plug portions 48 will protrude into the openings of compartments 34 and, if used, the openings of the vials 32 as well. The plug portions 48 are formed to releasably engage the compartments 34 or, if used, the vials 32. In particular, the frictional force between the plug portions 48 and the compartments 34 or the vials 32 will ensure that the vial pack cover 36 remains secured thereto such that material contained within the compartments 34 or vials 32 will remain therein.

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(13) The purpose of the barrier layer 50 is to ensure that the vial pack cover 36, and more specifically the plug portions 48, do not become degraded or damaged by the materials placed within the compartments 34 or the vials 32. In addition, barrier layer 50 will slow down or prevent the permeation of gasses from inside of the compartments 34 or vials 32 to the outside environment. In related devices that lack the barrier layer 50, not only are increased instances of cover degradation observed but also increased permeation of gasses through the cover 36. Gas permeation through the vial pack cover 36 leads to contamination of the surrounding environment as well as the degraded accuracy of the medical, chemical, or biotechnological test(s) being performed due to loss of the sample.

(14) As indicated above, silicone rubber is preferred as the material from which the vial pack cover 36 is formed because of its various characteristics. Specifically, silicone rubber is able to maintain its consistency and characteristics from temperatures as low as about -165 F. to as high as about 600 F. In addition, silicone rubber is clean when punctured inasmuch as a needle or syringe can penetrate the silicone without becoming contaminated with fragments of silicone. Moreover, once punctured by a needle or the like, silicone rubber is compliant and will re-seal.

The Examiner considers the addition of the barrier layer (50) of PTFE over the as meeting the limitation of a carrier sheet and the sealing elements being made of different materials since the sealing elements are coated while the rest of the sheet (42) is not.

6. Claims 13, 14, 20, 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Hafeman (6,074,614). Hafeman teaches a multiwell plate with a cover comprised of a bottom side with solid cylindrical projections extending downwardly from the flat bottom surface. Hafeman teaches a wide variety of general embodiments, but the embodiment most relevant to the instant claims is best shown in Figures 1 and 14 and described in column 13. The general embodiment is described in column 8:

(2) As shown in FIGS. 1 through 4, a preferred embodiment of the present invention has a cover 1. Cover 1 has ninety-six cylindrical projections 2 that are aligned with the corresponding ninety-six wells 3 of a multi-assay plate ("MAP") 4. Cylindrical projections 2 are centered about an optical axis passing down the

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axis of rotation of corresponding cylindrical wells 3, and parallel to axis Z--Z shown in FIG. 1. Cylindrical projections 2 have a diameter of 5.08 mm and a length of 7.20 mm extending from a flat bottom surface 12 of the cover 1. Wells 3 of MAP 4 are identified by corresponding letters A through H (that identify rows of wells 3 in MAP 4) and corresponding numbers 1 through 12 (that identify columns of wells 3 in MAP 4). The top surface 6 of cover 1 is flat. Further, cylindrical projections 2 are flat at their distal, bottom end 7.

(3) When the cover 1 is placed on MAP 4, the cylindrical projections 2 fit into wells 3. When wells 3 contain 200 ul of liquid samples 5, and cover 1 is placed on MAP 4, the bottom surfaces 7 of the projections 2 submerge just below the liquid level and displace liquid and bubbles to the side of the projections 2. When used in this intended manner, the cover of the present invention eliminates the meniscus effects and the problems associated therewith. In addition, the cover 1 eliminates the evaporation effect and the problems associated therewith.

(4) By way of example, the preferred cover 1 of the present invention may be cut and machined from a piece of clear polycarbonate and then lapped and vapor polished to increase optical clarity. The lapping and vapor polishing removes the small scratches and protrusions to reduce the wavelength-dependent light scattering.

(5) The cover 1 can be made of any suitable optically transparent material, e.g. polymethyl methacrylate, 4-methylpentene-1 based polyolefin (sold by Mitsui Petrochemical Industries, Ltd. of Toyko, Japan under the trademark TPX), polystyrene, polypropylene, plexiglass, glass, or quartz. In particular, it is contemplated that ultraviolet-radiation-transparent materials, e.g. ultraviolet-radiation-transparent polyethylenes, can be used to as the material from which to make the cover, as well as the MAP (see U.S. Ser. No. 08/228,415).

In column 13, Hafeman teaches an embodiment in which the protrusions from the bottom side of the cover also contain O-rings (column 13, lines 35-47). The Examiner considers a sealing element which includes an O-rings to be made of a different material than the cover (or sheet) and meeting the basic limitations of claim 13.

#### ***Allowable Subject Matter***

7. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 19 recites the addition of a top and bottom face to the groove

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element contained in the sealing element for engaging the carrier sheet. This feature was not shown nor suggested in the prior art found by the Examiner.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jordan et al. (4,960,219), McPherson et al. (5,096,676), Finney et al. (5,721,136), and Heimberg et al. (6,518,060) show flat array covers which are used to seal the tops of vessels in the arrays. Seguin et al. (6,136,273) and Feiglin (US 2001/0007642) teach covers for an array comprised of a mat with protruding hollow caps that are made of the same material as the mat. Malmqvist (6,432,694) displays a cartridge system for loading and sealing microplate wells with a cartridge tray placed over wells.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700

dkh

June 22, 2003